



## To study the efficacy of nalbuphine and fentanyl as adjuvants to epidural ropivacaine in lower abdomen and lower extremity surgeries in the patients attending tertiary care hospital, South India

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### Abstract

**Introduction:** Epidural adjuvants to local anaesthetics are used to enhance the quality and duration of surgical anaesthesia. The aim of this present study is to compare the clinical efficacy of Nalbuphine and Fentanyl as adjuvants to extradural ropivacaine for block characteristics and hemodynamic changes during lower abdominal & lower extremity surgeries. Specifically, the study compared Nalbuphine- 10mg and Fentanyl-50 $\mu$ g as adjuvants to extradural 0.75% (w/v) Ropivacaine in lower abdominal and lower extremity surgeries.

**Methodology:** This study consisted of 50 patients undergoing elective lower abdominal and lower extremity surgeries aged between 18-60 years, either gender, belonging to ASA grade I and II randomly divided into two groups by lottery method. After taking written informed consent from Patients, Patients were put to extradural catheterization with 16/18 G size and given extradural anaesthesia. At the end of the study the data is analyzed statistically using SPSS 24.0 Version. Diagrammatic representation, Descriptive data given as Mean  $\pm$  SD Continuous data analysis was done by t-test.

**Results:** By administering these two drugs for two different groups of patients, their efficacy regarding duration of analgesia, onset of sensory and motor block, maximum level of blockade, sedation, drug related side effects *viz.* pruritus, nausea, vomiting, hypotension, etc., hemodynamic changes, time for regression of blockade, and postoperative analgesia were observed. Nalbuphine is found to give more duration of analgesia than Fentanyl.

**Keywords:**Fentanyl, Nalbuphine, Extradural, Ropivacaine

## 1. Introduction

For lower extremity and lower abdominal procedures, regional anaesthesia provides many benefits over general anaesthesia as follows:

- Conscious patient
- Avoidance of polypharmacy
- No airway manipulation
- A substantial sensory and motor blockage
- Postoperative nausea and vomiting are less common.
- Optimal operational circumstances can be achieved.

Advantages of Extradural (epidural) Anaesthesia:

- If an extradural catheter is in situ, it offers efficient surgical anaesthesia and has no restrictions on the length of the procedure
- Offers sustained postoperative pain relief
- As it generates segmental anaesthesia, it lowers the likelihood of hemodynamic alterations brought on by asympathetic blocking.

Because the dura is not punctured, there is no PDPH incidence. Bupivacaine is being replaced as the preferred medication for extradural anaesthesia by modern long-acting local anaesthetics of the amide type levobupivacaine and ropivacaine. The distinction between ropivacaine and bupivacaine's structural similarities is the presence of a propyl group attached to the piperidine ring as opposed to a butyl group. The pure S-enantiomer ropivacaine is provided, in contrast to racemic bupivacaine. Ropivacaine has lower systemic toxicity and more differential blockade than racemic bupivacaine. A brand new long acting local anaesthetic called ropivacaine shares chemical similarities with bupivacaine and mepivacaine. The only difference between it and the S' enantiomer of Bupivacaine is that the tertiary nitrogen atom of the piperidine ring has a propyl group instead of a butyl group. It appears that ropivacaine might be a good local anaesthetic for extradural anaesthesia since it has all the benefits of bupivacaine with reduced cardiac and CNS toxicity. Levobupivacaine, L (-) isomer, and dextrobupivacaine, D (+) isomer, are split 50:50 in the commercial formulation of bupivacaine. A racemic mixture is a preparation that contains both enantiomers. To provide a greater margin of safety with the same analgesic efficacy and less postoperative motor block, racemic bupivacaine has been replaced with the S-enantiomer of ropivacaine. Ropivacaine is the more recent medications that compare favourably to bupivacaine in terms of hemodynamic stability and systemic toxicity.<sup>1-7</sup>

Fabricio de Oliveira, Frazilio *et al*<sup>8</sup> (2014) studied the effect of extradural nalbuphine on the minimum alveolar concentration of isoflurane (EtISO) and the postoperative analgesic requirements in dogs after ovariohysterectomy. The results showed that a significant decrease in EtISO was associated with extradural nalbuphine at 0.3mg/kg (26.3%) and 0.6mg/kg (38.4%) but not with saline. Goma, *et al*.<sup>9</sup> (2014) compared the peri-operative analgesic effects of intrathecal nalbuphine as well as fentanyl as adjuvants to bupivacaine in cesarean delivery. Participants were sixty pregnant women of ASA Grades I & II admitted for elective cesarean deliveries under spinal anaesthesia. The study found that the onset of motor block was significantly faster in fentanyl group as compared to nalbuphine group.

## 2. Material and Methodology

This study was carried out in the Department of Anaesthesiology in Government General Hospital of Guntur Medical College, Guntur from January 2021 to December 2022. The Hospital Ethical Committee has approved the study. This study consisted of 50 patients undergoing elective lower abdominal and lower extremity surgeries aged between 18-60 years, either gender, belonging to ASA grade I and II randomly divided into two groups by lottery method. After taking written informed consent from Patients, Patients were put to extradural catheterization with 16/18 G size and given extradural anaesthesia.

**Group RN:** The RN group consisted of 25 patients for whom 18ml of 0.75% Ropivacaine with Inj.

Nalbuphine 10mg (1ml) was administered extradurally.

**Group RF:** The RF group consists of 25 patients for whom 18ml of 0.75% Ropivacaine with Inj. Fentanyl 50µg (1ml) administered extradural.

**Inclusion criteria:** ASA grade I and II, aged between 18-60 years, belonging to both sexes undergoing lower abdominal surgeries and lower extremity surgeries.

**Exclusion criteria:** Patients who did not give consent for this study, Patients with ASA grade III, IV & Those who are allergic to local Anaesthetic drugs, Patients with local skin infection along spine, Patients with deformities of spine, Patients with coagulation defects and who are on anticoagulants, Uncooperative patients.

**Statistical analysis:**The data is analysed for statistical significance using SPSS 24.0 Version. Diagrammatic representation, Descriptive data analysed and represented by Mean  $\pm$  SD, Continuous data analysis was done by t-test.

### 3. Procedure

Pre anaesthetic check-up done to all patients and all patients were pre-medicated with 0.05mg/kg midazolam IM 1hr prior to the procedure.

The pulse rate, respiratory rate, blood pressure and SpO<sub>2</sub> were recorded before starting the case. 18G wide bore cannula placed and pre loading was done with ringer lactate 10ml/kg for all patients. 16G needle catheter introduced extradurally via needle into extradural space at least 3-4 cm and tapes are placed to secure it on back negative aspiration done to check any blood /CSF. 2% lignocaine (3ml) along with adrenaline (15µg) given and this is the test dose. Patient then kept in supine position checked for any adverse reactions of test dose till 5 minutes and then drugs can be administered.

Group RN (n=25), 18ml of (0.75%) Ropivacaine and Inj. Nalbuphine 10mg (1ml) extradurally given, Group RF (n=25), 18 ml of (0.75%) Ropivacaine and Inj. Fentanyl 50 µg (1ml) extradurally given.

Sensory block assessment done via bilateral pinprick method, motor block quality assessment via Bromage scale at intervals of 5, 10, 15, 20, 25, and 30 minutes.

Time of injection was recorded as 0 hour. In the two study groups, observations relating to the following were noted down: Sensory block-onset at T10 level, highest sensory level achieved, Maximum sensory level attainment time, Motor blocking onset time. Time for 2 segment regression, Sensory blocking duration, Motor blocking duration, Analgesia duration was recorded. SpO<sub>2</sub>/respiratory rate/heart rate were monitored, Hemodynamic variables (Systolic BP, diastolic BP, Mean Arterial Pressure, heart rate) were recorded every 5 min till 30 min, 15 min till 90 min their after 30 min till surgery ends, At start of surgery sedation score is recorded followed by every 20min all along the surgery, Side effects like nausea, vomiting, bradycardia/hypotension/respiratory depression/ dry mouth and shivering noted in the two study groups.

Sensory block – onset – taken from completion of injection of (Study drug) till now pin prick sensation by patient, Motor block-onset – taken from completion of injection of (Study drug) till no movement of feet by patient, Motor blockade-duration – taken from completion of injection of (Study drug) till motor block fall to bromage scale 1, Sensory blockade-duration – taken from completion of injection of (Study drug) till sensory block fall to T12 dermatomal level, analgesia duration- is taken from completion of injection of (study drug till patient has VAS(Visual Analogue Scale) score  $\geq$  4, If there was decreasing blood pressure  $>20\%$  beneath base line, even after administration of crystalloid Inj. Mephenteramine was given @ 6mg bolus dose. If pulse rate  $<30\%$  of baseline, Inj. Atropine (0.6mg) was given i.v. If respiratory rate  $<10$ /min diagnosed to be respiratory depression. At the end of the surgery the patients were shifted to post-operative ward, they were monitored for every 30 minutes for the first six hours and there after every hour for 24 hours period. To relieve pain top up of 10 ml of 0.2% Ropivacaine was given.

### 4. Results

Of the fifty patients, 25 belong to group RN (18ml of 0.75%-Ropivacaine along with Inj.Nalbuphine-10mg (1ml) and the remaining 25 patients belong to group RF (18ml of 0.75%-

Ropivacaine along with Inj.Fentanyl 50µg/kg (1ml).

**TABLE1: DISTRIBUTION OF AGE AMONG THE STUDY PARTICIPANTS**

AGE IN YEARS	GROUP RN	GROUP RF
18-27	2	1
28-37	5	8
38-47	8	7
48-57	7	8
>57	3	1
Total	25	25
MEAN	44.8	42.72
S.D.	10.92	10.68

The age distribution among the RN-group was 22-60 years, RF-group was 18-59 years and their mean ages with standard deviation are 44.8 and 42.7 with standard deviation 10.92 and 10.68.

**TABLE 2: TYPES OF SURGERIES AMONG THE TWO STUDY GROUPS**

TYPE OF SURGERY	GROUP RN	GROUP RF
Appendicectomy	3	3
Below knee amputation	2	2
Bilateral inguinal hernia	2	3
CRIF of femur and tibial fractures	3	2
Incisional hernia	2	3
ORIF of tibial condyle	2	2
Patellectomy	1	2
Unilateral Inguinal hernia	1	1
Total abdominal hysterectomy	4	4
Varicose veins	4	3
TOTAL	25	25

Total abdominal hysterectomy, varicose veins repair followed by hernia repair are the most common surgeries performed among both the study groups.

**TABLE 3: COMPARISON OF DURATION OF ONSET OF SENSORY BLOCKADE**

GROUP	MEAN	SD	P-Value
RN	9.84	1.43	0.00000001
RF	13.32 (p<0.05)	2.43	

Mean time required for onset-sensory blockade to T10 level, in group RN was 9.84 ± 1.43 min, in group RF was 13.32 ± 2.43 min. The result showed statistically significant difference p=0.0000001 (<0.01) between the two groups.

**TABLE 4: COMPARISON OF DURATION OF ONSET OF MOTOR BLOCKADE**

GROUP	MEAN	SD	P-VALUE
RN	17.68	1.93	0.10
RF	18.8	2.74	

Mean duration onset of-motor blockade in group RN was 17.68 ± 1.93 mins, in group RD was 18.8 ± 2.74 mins. This was statistically insignificant p = 0.10 in the two groups.

**TABLE 5: COMPARISON OF DURATION OF MOTOR BLOCKADE**

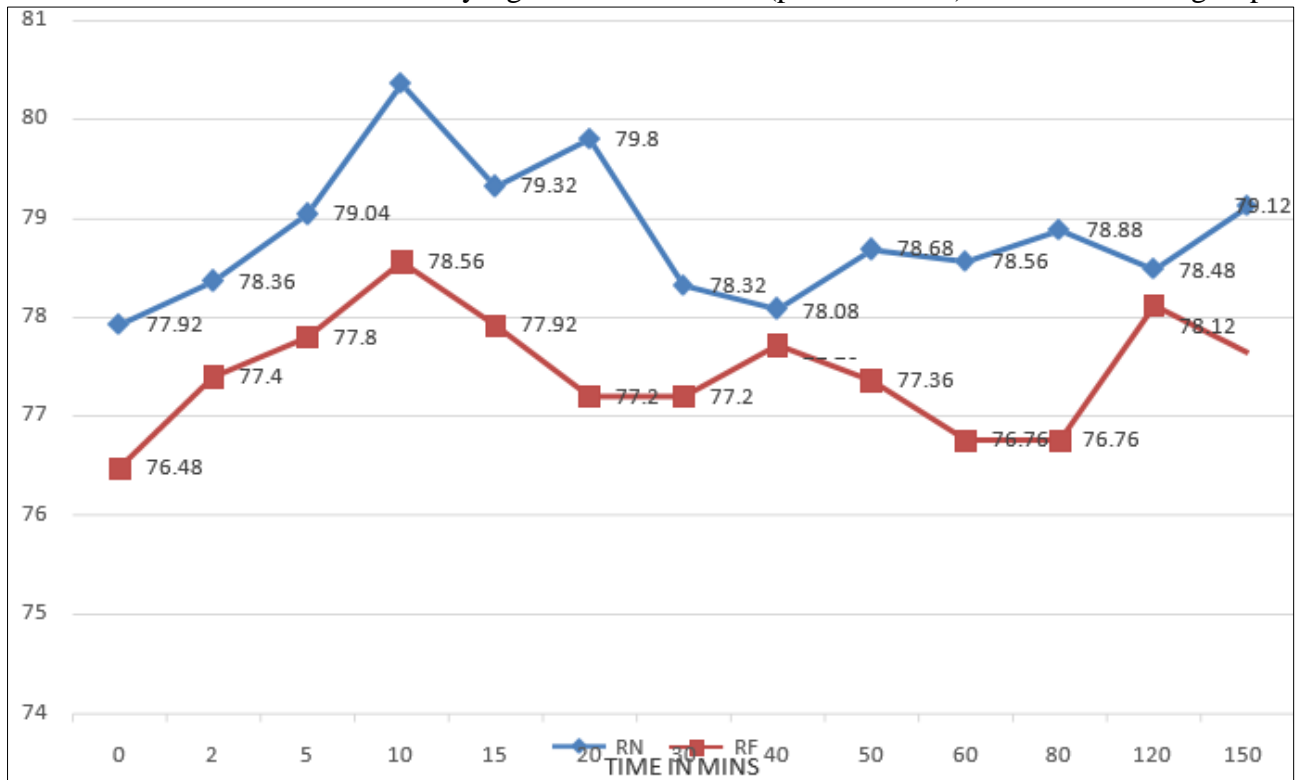
GROUP	MEAN	S D	P-VALUE
RN	180.96	12.95	0.0001
RF	167.80	8.74	

The mean duration of motor blockade in group RN was  $180.96 \pm 12.95$  mins, in group RF was  $167.80 \pm 8.74$  mins. This result was statistically significant  $p=0.0001 (<0.01)$  in the two groups.

**TABLE 6: COMPARISON OF DURATION OF SENSORY BLOCKADE**

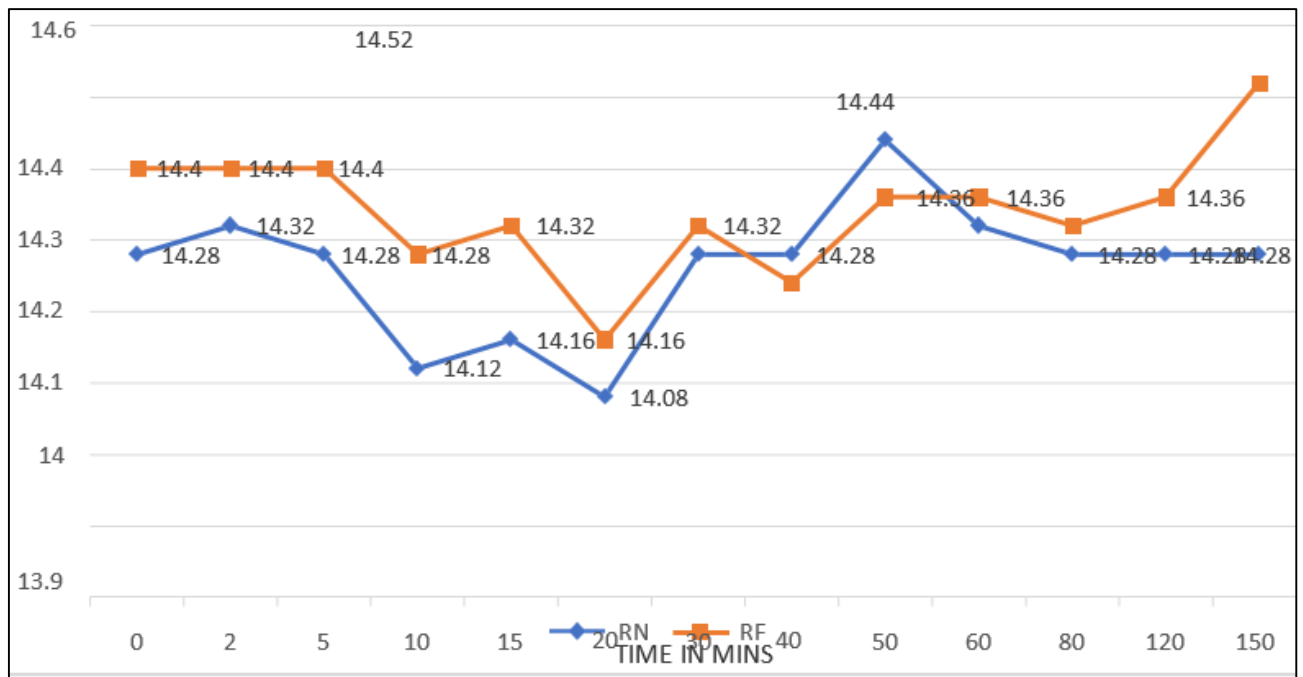
GROUP	MEAN	S D	P-VALUE
RC	275.72	20.57	0.0001
RD	218.24	11.00	

The mean duration of sensory block in group RN was  $275.72 \pm$  mins, in group RF was  $218.24 \pm$  mins. This result showed statistically significant difference ( $p0.0001<0.01$ ) between the two groups.



**FIG 1: COMPARISON OF HEART RATE BETWEEN RN AND RF**

Intra-operatively the base line (0 mins) heart rate in the RN and RF group was  $77.92 \pm 8.57$  and  $76.48 \pm 8.11$  and during the 150 mins it was  $79.12 \pm 8.56$  and  $77.64 \pm 7.81$ . The observed results do not have any statistical significance.



**FIG 2: COMPARISON OF RESPIRATORY RATE BETWEEN RN AND RF**

Intra-operatively the baseline (0mins) respiratory rate in RN and RF groups were  $14.28 \pm 1.24$  and  $14.40 \pm 1.32$  and during the 150 mins it was  $14.28 \pm 1.21$  and  $14.52 \pm 1.23$ . The observed results were not statistically significant.

**TABLE 7: COMPARISON OF SEDATION SCORES AMONG THE STUDY GROUPS**

TIME		SEDATION SCORES	
		1-2	3-5
0-6HRS	GROUP RN	3(12%)	22(88%)
	GROUP RF	21(84%)	4(16%)
6-12HRS	GROUP RN	4(16%)	21(84%)
	GROUP RF	22(88%)	3(12%)
12-24HRS	GROUP RN	6(24%)	19(76%)
	GROUP RF	23(92%)	2(8%)

**TABLE 8: COMPARISON OF SIDE EFFECTS AMONG BOTH THE STUDY GROUPS**

SIDE EFFECTS	GROUP RN (N =25)	GROUP RF (N =25)
Bradycardia	2(8%)	1(4%)
Hypotension	2(8%)	2(8%)
Nausea	5 (20%)	2(8%)
Vomiting	2(8%)	0
Shivering	0	1(4%)
Pruritus	2(8%)	5 (20%)
Respiratory Depression	0	0

Sedation was observed to be better in RF group in 0-6hrs, 6-12hrs and 12-24hrs window periods than RN group.

The major side effects observed among the RN group is nausea 5(20%) and among the RF group is Pruritus 5 (20%).

**5. Discussion**

Regional techniques, such as spinal and extradural anaesthesia may offer advantages over general anaesthesia including reduced stress response to surgery and analgesia, which generally extends into the

postoperative period.

Onset- of sensory-blockade is taken as time from the completion of injection of study drug till the patient not feel pin prick sensation at T12 level. In this study mean time for onset-of-sensory blockade at T12 in Group RN was significantly less than Group RF (GROUP RN  $10.4 \pm 1.38$  min, GROUP RF  $12.84 \pm 1.72$  min,  $p < 0.05$ ). Babu *et al.* [10](2017) compared the efficacy of butorphanol 2mg and nalbuphine 10mg as adjuvant to 0.2% ropivacaine for postoperative pain as thoracic extradural analgesia in emergency laparotomy and concluded that the time- of – onset of analgesia was faster with nalbuphine than butorphanol. Kamel *et al.* [11] (1999) compared the effects of extradural nalbuphine and clonidine added as adjuvants to bupivacaine for full term primigravida in labor. The shortest onset of analgesia was recorded in bupivacaine nalbuphine group. Thus, the results of the present study coincided with the findings of the above mentioned past two studies conducted by Babu *et al.* and Kamel *et al.* who stated that nalbuphine has faster onset compared to fentanyl. The present study found that the dose of fentanyl-50 $\mu$ g has faster onset when compared with other doses of fentanyl. Dhale and Shelgaonkar<sup>6</sup> (2000) also studied different doses of extradural fentanyl (25 $\mu$ g, 50 $\mu$ g, 75 $\mu$ g) with 0.5% bupivacaine and found that 50 $\mu$ g has quicker onset of analgesia. The duration of motor blockade was comparable in both groups. Gupta *et al.*<sup>12</sup> in their study comparing the intrathecal 0.5% hyperbaric bupivacaine 3.5ml with fentanyl (25mcg), nalbuphine 2mg in lower extremity orthopedic surgeries showing mean total duration of-motor-blockade in FB group is  $141.63 \pm 18.05$  min and in BN group  $183.26 \pm 21.92$  min with p value 0.003. In the present study, mean HR, RR and SBP in both the groups were compared and it was observed that P-value were insignificant between two groups. In the present study mean DBP in both groups were compared and was observed that there is a difference which is statistically significant among both groups at 20 mins and 1 hour with a lower mean DBP in RN group than RF group. The mean arterial pressures in two groups were compared and were observed that there is a difference which is significant among both groups at 60 mins with a lower MAP in RN group than RF group. Mean sedation scores were significantly higher in RN group compared to RF group as 22% patients in group RN observed sedation scores of 3-5 on comparison with 4% in group RF ( $p < 0.0001 < 0.01$ ). Only 3% of patients in the RN group observed sedation scores of 1-2 compared to 21% widely in RF group, which has a high statistical significance ( $p < 0.0001 < 0.01$ ). Patients who were administered with nalbuphine as adjuvant experienced more nausea & vomiting compared to fentanyl., Whereas pruritus was most seen with fentanyl group than nalbuphine group. All other side effects were equally occurring between two groups.

## 6. Conclusion

This study concludes that Nalbuphine is a better adjuvant than Fentanyl in extradural anaesthesia as far as patient comfort, stable cardio-respiratory parameters, intra- operative and post-operative analgesia is concerned. Overall the experience with Nalbuphine was quite satisfactory as compared to Fentanyl because of its superior sedative and anxiolytic properties during the surgical procedure under regional anaesthesia

**7. Conflict of interest:** None to be declared

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